UNITED STATES PATENT AND TRADEMARK OFFICE

In re Sanofi-Aventis

Request for Patent Term Extension

U.S. Patent No. 4,661,491

ORDER GRANTING

INTERIM EXTENSION

Sanofi-Aventis, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,661,491, filed an application under 35 U.S.C. § 156(d)(1), requesting an extension of 1,481 days. The original expiration date of the patent is May 27, 2006. The patent claims a method of use of the approved drug product, alfuzosin hydrochloride (Uroxatral®). The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 505(i) and 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360e) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, an interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,661,491 is granted for a period of one year from the original expiration date of the patent, i.e., until May 27, 2007.

Date

Jon W. Dudas

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office